## In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS No. 21-1237V Filed: January 24, 2025

JACK ROBERT DAY.

**Special Master Horner** 

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for petitioner. Tyler King, U.S. Department of Justice, Washington, DC, for respondent.

### RULING ON ENTITLEMENT<sup>1</sup>

On April 16, 2021, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa, *et seq.* (2012), alleging that he suffered a Table Injury of a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccination he received on September 27, 2018. (ECF No. 1.) In an amended petition filed April 25, 2023, petitioner alternatively pleaded causation-in-fact. (ECF No. 42.) For the reasons set forth below, I conclude that petitioner is entitled to compensation for a Table SIRVA.

### I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

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<sup>&</sup>lt;sup>1</sup> Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists SIRVA as a compensable injury if it occurs within ≤48 hours of administration of a flu vaccine. § 300aa-14(a) as amended by 42 C.F.R. § 100.3. Table Injury cases are guided by a statutory "Qualifications and aids in interpretation" ("QAI"), which provides more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. § 300aa-14(a). To be considered a Table SIRVA petitioner must show that his/her injury fits within the following definition:

SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of

radiculopathy, brachial neuritis, mononeuropathies, and any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner could still demonstrate entitlement to an award by instead showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). To successfully demonstrate causation-in-fact, petitioner bears a burden to show: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non–Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 300aa-13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; see also Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3(b)(1). Special masters must ensure each party has had a "full and fair opportunity" to develop the record. Vaccine Rule 3(b)(2). However, special masters are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or

death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. Winkler v. Sec'y of Health & Human Servs., 88 F.4th 958, 963 (Fed. Cir. 2023) (citing Hines ex rel. Sevier v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

### II. Procedural History

At the time of petition filing, petitioner was represented by different counsel. (ECF No. 1.) Current counsel of record entered the case on January 10, 2023. (ECF No. 35.) Between April of 2021 and March of 2022, petitioner filed an affidavit (marked as Exhibit 1) as well as medical and other records (marked as Exhibits 2-7). (ECF Nos. 1, 12, 19-20.) He filed a statement of completion on March 22, 2022. (ECF No. 21.) Updated medical records (marked as Exhibit 8) were also subsequently filed. (ECF No. 22.) The parties initially explored settlement within the Special Processing Unit ("SPU"). (ECF Nos. 8-9, 28.) However, the case was reassigned to me in April of 2023, after the parties advised the Chief Special Master that settlement did not appear feasible. (ECF Nos. 40-41.)

After the case was reassigned, petitioner filed additional medical records and witness statements (marked as Exhibits 9-12), and respondent filed his Rule 4 Report. (ECF Nos. 45-46.) Based on review of respondent's report, I scheduled a video fact hearing, which was held on August 22, 2023. (See Transcript of Proceedings ("Tr."), at ECF No. 51.) Petitioner testified along with two additional fact witnesses. (*Id.*) Subsequently, additional medical records (marked as Exhibits 13-17) were filed. (ECF Nos. 59, 62.)

Thereafter, petitioner was directed to file a motion for a ruling on the written record, which he did on April 4, 2024. (ECF No. 64; NON-PDF Scheduling Order, filed March 5, 2024.) Respondent filed his response on May 6, 2024. (ECF No. 65.) Petitioner filed additional medical records (marked as Exhibits 18-19) on May 8, 2024, and a reply brief on May 20, 2024. (ECF Nos. 66-67.) In the motion, the parties addressed petitioner's alleged Table Injury claim as well as his alternative cause-in-fact allegation. However, petitioner also requested that "[i]f the Court should decide that expert involvement is necessary to assess Petitioner's off-table SIRVA claim, then Petitioner would request leave to obtain an expert report." (ECF No. 64, p. 2.) In his response, respondent contended that petitioner's medical records are inadequate to support a cause-in-fact claim and further noted that no expert report was in evidence. (ECF No. 65, pp. 11-12.) In reply, petitioner maintained that his medical records are adequate to establish causation-in-fact, but also further stressed that "the parties have not been afforded the opportunity to seek expert opinion in this case. (ECF No. 67, p. 1.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases, and that it is appropriate to resolve entitlement on the

existing record, with respect to petitioner's alleged Table Injury claim only. See Vaccine Rule 8(d); Vaccine Rule 3(b)(2); see also Kreizenbeck v. Sec'y of Health & Human Servs., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record").

### **III.** Factual History

Petitioner was 56 years old when he received the flu vaccination at issue in this case on September 27, 2018, in his left deltoid. (Ex. 2, p. 6.) Petitioner had a history of several chronic conditions, but respondent has not suggested that he had any relevant prior shoulder symptoms or conditions. (Tr. 8-9, 24; ECF No. 65, p. 2.)

Petitioner testified that prior to receiving the vaccination at issue, he had no major pain, discomfort, or limitations with his left shoulder. (Tr. 10.) He explained that "[i]mmediately following the injection I had knife-like extreme pain in my arm, something I had never experienced before, intense, unlike any other vaccine shot I've ever had." (Id. at 10-11.) The initial, sharp pain subsided, but continuous pain remained and resulted in loss of mobility in the arm. (Id. at 11, 13.) Daily activities, like cleaning, washing dishes, and grocery shopping, aggravated his shoulder. (Id. at 14.) He also determined that he could not continue driving, because he did not think he could drive safely with just his right arm.<sup>2</sup> (Id.) In his first affidavit, petitioner had indicated that onset of reduced range of motion occurred the day after vaccination. (Ex. 1, ¶ 4.) During the hearing, however, petitioner disagreed with that statement and testified that he had reduced range of motion on the same day as the vaccination. (Tr. 73-74.) At the time of vaccination, he was already taking 500mg of naproxen for other issues. (Id. at 12.) After the vaccination, he also began taking 1,000mg of Tylenol. (Id. at 12-13.) The Tylenol provided some, but not complete, relief. (Id. at 14.) With respect to pain and medical issues, petitioner explained that it has been his habit and practice throughout his life "to wait for it to go away" before seeking medical care. (Id. at 13-14.)

Petitioner's neighbor, Joseph Maresh, also testified. (Tr. 95-97.) Mr. Maresh testified that on a couple of occasions in the Autumn of 2018, between late October and Christmas, he asked petitioner for a ride (petitioner was an Uber driver) and petitioner "complained that he couldn't drive because of a problem with his shoulder, his arm, a lot of pain." (*Id.* at 98, 105.) Mr. Maresh also described helping petitioner with taking out trash or carrying laundry baskets to the laundry room. (*Id.* at 98-99.) Most of the help he provided was between October and December. (*Id.* at 100.) However, Mr. Maresh also testified that he recalled seeing petitioner in pain in September and October. (*Id.* at 103.) He recalled that petitioner wasn't driving much at that time, that petitioner

<sup>&</sup>lt;sup>2</sup> On cross-examination, petitioner indicated that he did not completely lose the ability to drive. In response to respondent's questions, he indicated that he did manage to drive home from his vaccination despite experiencing difficulty with it and further that he felt he regained the ability to drive after about a month. (Tr. 47-48.) After that, petitioner still found it painful to drive, but could still do it as needed. (*Id.* at 48.) On further questioning, petitioner acknowledged driving to a medical encounter occurring about two weeks post-vaccination. (*Id.* at 50-51.) Later during the hearing, he indicated he could not drive for approximately ten days following the vaccination. (*Id.* at 72.)

appeared to have slowed down, and that petitioner "constantly told me he was in pain." (*Id.* at 101-02.) Mr. Maresh confirmed that petitioner attributed his shoulder condition to an injection but stated "I didn't question anything else about it. I just took his word that something happened when he got a shot." (*Id.* at 99.) He explained that "I didn't know the man that well to ask any more personal questions, but I could see he was in a lot of pain and agony at the time. That's about all I know." (*Id.* at 102.) Mr. Maresh specifically recalled helping petitioner take out his trash in mid-September. (*Id.* at 107-08.) He noted that, whatever had happened to petitioner, "it took a lot out of him." (*Id.* at 110.)

Petitioner underwent a sleep study on October 11, 2018, for evaluation of sleep apnea. (Ex. 3, p. 383.) He testified that his shoulder was still painful at that time and, as a result, he slept on his back for the sleep study, instead of on his left shoulder, which was customary for him. (Tr. 20-21.) Petitioner testified that he asked the technician if his shoulder problem would affect the efficacy of the study. (*Id.* at 16-17.) He was told to ask the pulmonologist. (Id. at 17.) However, no mention of shoulder pain is documented in the record of the sleep study (Ex. 3, pp. 383-89), though petitioner also testified that the technician did not do any physical exam or take any history from him. (Tr. 16.) Nonetheless, the sleep study required completion of a patient questionnaire on which petitioner marked that he had no joint pain or muscle cramps under the musculoskeletal section of the questionnaire. (Ex. 3, p. 397.) Additionally, although petitioner testified that his shoulder pain interfered with his ability to fall and stay asleep (Tr. 51), he did not mark on the questionnaire, where prompted, that he had difficulty falling asleep or maintaining sleep. (Ex. 3, p. 395.) He also did not check-mark "pain in the limbs or back" as issues that wake him during sleep. (Id. at 396). However, he did testify that the shoulder pain did wake him up (Tr. 61). During the hearing, petitioner could not recall filling out the questionnaire, but reasoned that the lack of any specific prompt regarding the shoulder was the reason his shoulder issues were not reflected on the questionnaire. (*Id.* at 54, 57.)

Petitioner's medical records include an encounter record from October 26, 2018, which notes that petitioner left without being seen. (Ex. 3, p. 407.) However, in an affidavit filed in this case, petitioner stated that he had mentioned his shoulder pain at this encounter and stated, "I remember specifically explaining that I was surprised the pain from the vaccination had not yet gone away." (Ex. 10, ¶ 5.) During the hearing, petitioner could not recall the details or purpose of the encounter. (Tr. 58-60.) However, he did indicate that this was not a "full medical visit" at which his symptoms were evaluated. (*Id.* at 78-79.) He felt it was most likely a blood pressure check. (*Id.* at 58-60, 79.)

Petitioner had a follow up encounter to discuss results of his sleep study on October 30, 2018. (Ex. 3, p. 411.) Petitioner testified that he asked the pulmonary specialist whether his shoulder pain and sleeping position would have affected the study and was told that this issue did not impact the results of the study. (Tr. 18-19.) Again, neither this discussion, nor any report of shoulder pain, is included in the October 30, 2018 medical record. (Ex. 3, pp. 411-17.) Petitioner stressed his reports of shoulder

pain were with respect to the efficacy of the study and that he did not expect to undergo any physical exam as a result of his mentioning of shoulder pain. (Tr. 19-20.) Asked on cross-examination why his shoulder complaints are not reflected in this medical record, petitioner reasoned that "maybe it wasn't relevant" to the pulmonologist. (*Id.* at 63.)

On November 6, 2018, about 40 days post-vaccination, petitioner returned to his primary care provider for follow up regarding some of his chronic conditions. (Ex. 3, pp. 427-32.) Petitioner testified that this appointment was to check bloodwork for his thyroid and was scheduled prior to the time he received the vaccination at issue. (Tr. 21.) Left shoulder pain was not recorded at this encounter, though the Review of Systems documented screening only for constitutional, cardiovascular, and endocrine issues. (Ex. 3, p. 428.) The physical exam portion of the encounter record indicates "Musculoskeletal: He exhibits no edema." (Id. at 430.) Petitioner was instructed to follow up again in six months. (Id. at 431.) None of the visit diagnoses from this encounter pertain to petitioner's shoulder. (Id. at 432.) Petitioner testified, however, that, although the purpose of the encounter was solely follow up for his hyperthyroidism, he did mention his shoulder pain to his provider, though he specifically noted that he told her he still believed it would go away on its own. (Tr. 22-23.) He indicated that she did not respond and that she did not perform any physical exam of his left shoulder. (Id. at 23.) Petitioner testified that, in his experience, doctors do not respond to complaints that are outside of their area of concern or practice. (Id.) Petitioner also had a mental health counseling session on November 19, 2018, at which no mention of shoulder pain was recorded. (Ex. 3, p. 435.)

Petitioner testified that he spent Thanksgiving that year at his mother's home. (Tr. 46.) At that time, he told his sister-in-law, Cathy DiEgidio, about his shoulder pain. (Id.) Specifically, he told her he could not lift some of the items at the gathering because of his pain and mobility issues. (Id. at 46-47.) He testified that, at that time, he still felt that the pain would go away on its own and that he did not discuss any past or future treatment with Ms. DiEgidio, apart, perhaps, from the fact that he was taking Tylenol. (Id. at 49.) Ms. DiEgidio also testified during the hearing. (Id. at 83.) She testified that petitioner "relayed to me during – I believe it was Thanksgiving – and just in general conversation that his arm was sore from a flu shot that he had received, and it was just, you know, passing conversation at holiday time." (Id. at 85.) She did not observe him in any kind of pain, and did not discuss his level of pain, but did recall that he didn't understand why his shoulder was still sore. (Id. at 86-87.)

On January 9, 2019, about three and a half months post-vaccination, petitioner presented to a sports medicine specialist, Dr. Morton. (Ex. 3, p. 442.) Petitioner presented by self-referral<sup>3</sup> and his chief complaint was "[l]eft shoulder pain and limited [range of motion]." (Id.) Petitioner reported a "3 month" history of left lateral shoulder

<sup>&</sup>lt;sup>3</sup> Petitioner testified that he needed a referral to see a specialist and did receive a referral after his November 6, 2018 encounter. (Tr. 27-28.) On cross-examination he indicated that the referral came from Dr. Whited, who he saw on November 6, 2018. (Id. at 70.) However, petitioner did not see the record of the referral. (Id.) He indicated that he was told it was an internal document that existed within a database but could not be retrieved. (Id.) Nonetheless, Dr. Morton's record indicates petitioner presented based on a self-referral. It is not necessary to resolve this seeming conflict.

pain and that "he immediately [h]ad pain after his last flu shot into the left shoulder and the pain has not improved." (*Id.*) It is further noted that "[h]e has difficulty with all overhead movements. He was moving his left shoulder through a full [range of motion] without pain before injection." (*Id.*) Review of Systems noted "Left shoulder pain" under musculoskeletal. (Ex. 3, p. 443.) Petitioner underwent a cervical spine exam, a neurologic exam, and a left shoulder exam. (*Id.* at 446.) Dr. Morton recorded his impression as "[v]accination related Injury to Left shoulder (rotator cuff) causing Impingement Syndrome/Limited Mobility." (*Id.*) Petitioner testified that Dr. Morton expressed familiarity with the phenomenon of post-vaccination shoulder injuries and that he had seen prior patients with the same issue. (Tr. 29.) Petitioner was prescribed Toradol, and an x-ray was ordered. (Ex. 3, p. 446.) An MRI would be considered if symptoms did not improve. (*Id.*) The x-ray was unremarkable apart from mild acromioclavicular arthrosis. (*Id.* at 450.)

Petitioner was subsequently seen by an orthopedist on January 28, 2019. (Ex. 3, p. 465.) He had other unrelated encounters in the interim. (*Id.* at 452-64.) The reason for petitioner's orthopedic encounter was listed as follow up regarding left knee and ankle pain; however, petitioner also complained of left shoulder pain that "started to bother him following a vaccine placed 3 months prior." (*Id.* at 465.) Following a physical exam of the left shoulder and review of the prior x-ray, the orthopedist assessed petitioner for left shoulder supraspinatus tendinopathy and recommended physical therapy. (*Id.* at 468-69.) During the hearing, petitioner could not recall this encounter. (Tr. 32.)

Thereafter, petitioner continued to seek follow up care for his shoulder, albeit with some gaps in documented care. However, given the arguments presented by the parties, it is not necessary to discuss the course of petitioner's care in full, though I have reviewed all of the records. In particular, respondent has not suggested that petitioner ever provided a contradictory history of onset of his left shoulder pain or that any findings in petitioner's subsequent history are incompatible with the presence of a SIRVA. (ECF No. 65.) Petitioner eventually underwent a left reverse shoulder replacement surgery on October 17, 2023. (Ex. 15, pp. 7-9; Ex. 18, p. 52.)

### IV. Party Contentions

Petitioner's motion proposes in pertinent part that I resolve two questions in petitioner's favor: whether there is preponderant evidence that petitioner's left shoulder pain began within 48-hours of his vaccination and whether there is preponderant evidence that petitioner has satisfied all the QAI requirements for a Table SIRVA. (ECF No. 64, pp. 1-2.) In the motion, petitioner sets forth in detail why, in his view, the record evidence supports a finding as to each of the four SIRVA QAI criteria. (*Id.* at 16-31.) Petitioner further stresses that his treating physicians consistently linked his shoulder symptoms to his vaccination and argues that this should be viewed as "quite probative." (*Id.* at 31-36 (citing *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009)).)

Respondent argues, however, that petitioner has not demonstrated a Table SIRVA, because he has not preponderantly established that the onset of his shoulder pain occurred within 48-hours of vaccination. (ECF No. 65, p. 9.) Respondent does not raise any other opposition to petitioner's assertion of a Table SIRVA.<sup>4</sup> (*Id.* at 8-10.) Respondent explains that petitioner did not have any medical appointment following his vaccination until his November 6, 2018 primary care encounter.<sup>5</sup> (*Id.* at 9 (citing Ex. 3, p. 427).) He stresses that no complaint of shoulder pain was raised at that encounter and that the record indicates that a musculoskeletal physical exam was normal. (Id. (citing Ex. 3, pp. 429-30).) Although petitioner referenced a three-month history of shoulder pain at a January 9, 2019 encounter occurring 104 days post-vaccination, that history is inconsistent with the record of his November 6, 2018 encounter. (Id. at 10 (comparing Ex. 3, p. 442 and Ex. 3, p. 427).) Respondent cites several prior cases for the proposition that this type of circumstance does not support a 48-hour onset of shoulder pain. (Id. (citing Rose v. Sec'y of Health & Human Servs., No. 20-56V, 2022 WL 4128908, at \*3 (Fed. Cl. Spec. Mstr. Aug. 10, 2022); Bulman v. Sec'y of Health & Human Servs., No. 19-1217V, 2021 WL 4165349, at \*4 (Fed. Cl. Spec. Mstr. Aug. 12, 2021); Pitts v. Sec'y of Health & Human Servs., No. 18-1512V, 2020 WL 2959421, at \*5 (Fed. Cl. Spec. Mstr. Apr. 29, 2020)).)<sup>6</sup> Respondent contends that petitioner's testimony that he reported shoulder pain to his physicians that went unrecorded has no supporting explanation and "defies logic." (Id.)

In reply, petitioner argues that the cases cited by respondent are not applicable to this case. (ECF No. 67, pp. 6-9.) He explains why, in his view, each case is distinguishable. (Id. at 7-9.) In contrast, he cites several other cases for the proposition that petitioner's delay in seeking treatment is not unusual and that neither a delay in seeking treatment nor intervening medical encounters are dispositive of the question of onset. (Id. at 9-15 (citing Bergtstom v. Sec'y of Health & Human Servs., No. 19-784V,

<sup>&</sup>lt;sup>4</sup> During a status conference with the Chief Special Master held April 4, 2023, respondent represented that in addition to the timing of onset, respondent also intended to contest that petitioner's complaints were not limited to the shoulder in which he received the vaccination and that there are other potential intervening causes to explain petitioner's condition. (ECF No. 40, p. 2.) However, respondent did not subsequently raise either of these other potential issues in either his Rule 4 Report or his response to petitioner's motion. (ECF Nos. 46, 65.) Accordingly, respondent has not preserved these issues for consideration and instead appears to have abandoned them. Vaccine Rule 8(f)(1) ("Any fact or argument not raised specifically in the record before the special master will be considered waived . . . . "); Coombes v. Sec'y of Health & Human Servs., No. 21-1750V, 2024 WL 4625130, at \*7 (Fed. Cl. Spec. Mstr. Sept. 24, 2024) (noting with respect to respondent's Rule 4 Report that "the Vaccine Rules do not contemplate respondent raising piecemeal objections to compensation, reserving additional issues for later").

<sup>&</sup>lt;sup>5</sup> Although petitioner's sleep study, follow up with the pulmonologist, and October 26, 2018 encounter, were all addressed during the fact hearing, respondent does not discuss any of these encounters in either his motion response or his Rule 4 report. (ECF Nos. 46, 65.)

<sup>&</sup>lt;sup>6</sup> It should be noted with respect to the *Pitts* case that respondent cites the Chief Special Master's finding of fact issued in April of 2020; however, the case was subsequently reassigned to me and I found it necessary to revisit the Chief Special Master's finding of fact in ultimately deciding the case. Pitts v. Sec'y of Health & Human Servs., No. 18-1512V, 2023 WL 2770943 (Fed. Cl. Spec. Mstr. Apr. 4, 2023). Although I reached the same conclusion with regard to the timing of onset, the reasoning was not the same in all regards. Id. at 8-10.

2020 WL 8373365, at \*3 (Fed. Cl. Spec. Mstr. Dec. 4, 2020); Merwitz v. Sec'y of Health & Human Servs., No. 20-1141V, 2022 WL 17820768, at \*3-4 (Fed. Cl. Spec. Mstr. Oct. 11, 2022); Williams v. Sec'y of Health & Human Servs., No. 17-830V, 2019 WL 1040410, at \*9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019); Boyd v. Sec'y of Health & Human Servs., No. 19-1107V, 2021 WL 4165160, at \*3 (Fed. Cl. Spec. Mstr. Aug. 12, 2021); Dempsey v. Sec'y of Health & Human Servs., No. 18-970V, 2021 WL 1080563, at \*4 (Fed. Cl. Spec. Mstr. Feb. 17, 2021); Egger v. Sec'y of Health & Human Servs., No. 19-98V, 2022 WL 5237090, at \*6 (Fed. Cl. Spec. Mstr. Aug. 29, 2022); Kleinschmidt v. Sec'y of Health & Human Servs., No. 20-680V, 2023 WL 9119039 (Fed. Cl. Spec. Mstr. Dec. 5, 2023); Cain v. Sec'y of Health & Human Servs., No. 19-1917V, 2022 WL 4459416, at \*9 (Fed. Cl. Spec. Mstr. Aug. 31, 2022); Heiner v. Sec'y of Health & Human Servs., No. 19-1339V, 2022 WL 4457901, at \*11 (Fed. Cl. Spec. Mstr. Aug. 29, 2022)).) Petitioner argues that the fact that shoulder pain was not reported at intervening encounters during October and November of 2018 is not dispositive because they were for specific purposes unrelated to petitioner's orthopedic complaint. (Id. at 15.) Once petitioner commenced treatment of his condition, his records are consistent and unequivocal with regard to a post-vaccination onset. (*Id.* at 16.)

## V. Analysis

# a. SIRVA QAI Criterion (ii) – Pain occurs within the specified time-frame (48 hours)

In order to establish that his injury constitutes a Table Injury of SIRVA, petitioner must demonstrate that he experienced the onset of his shoulder pain within 48 hours of vaccination. 42 C.F.R. § 100.3(a)(XIV)(B). This is the primary issue presented by the parties.

Pursuant to the Vaccine Act, § 300aa-13(a)(1)(A), a petitioner must prove their claim by a preponderance of the evidence. A special master must consider the record as a whole, but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 300aa-13(b)(1). However, the Federal Circuit has held that contemporaneous medical records are ordinarily to be given significant weight due to the fact that "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Yet, this precept is not absolute. *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (stating that "[w]e reject as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions"). Medical records are afforded substantial weight when they are clear, consistent, and complete. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at \*1, 19-20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Afterall,

"[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs.*, No. 03-1192V, 2006 WL 2252749, at \*2 (Fed. Cl. Spec. Mstr. July 18, 2006). Importantly, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992).

When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." Camery v. Sec'y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (citing Blutstein v. Sec'y of Health & Human Servs., No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the special master must consider the credibility of the individual offering the testimony. Andreu, 569 F.3d at 1379; Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 416-17 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence" contained in the record. La Londe v. Sec'y Health & Human Servs., 110 Fed. Cl. 184, 204 (2013) (citing § 300aa-12(d)(3); Vaccine Rule 8), aff'd sub nom. La Londe v. Sec'y of Health & Human Servs., 746 F.3d 1334 (Fed. Cir. 2014); see also Burns, 3 F.3d at 417.

In this case, when petitioner first presented for care of his alleged SIRVA, the contemporaneous treatment record confirms that he explicitly reported to his doctor that he experienced pain "immediately" following the vaccination at issue, consistent with the Table requirement. (Ex. 3, p. 442.) However, this encounter did not occur until over three-months after the vaccination. (Id.) As respondent observes, petitioner's medical records reflect that he did not seek treatment for his shoulder pain promptly or at the first opportunity. Nonetheless, petitioner is correct in noting that neither of these factors is dispositive in itself. E.g. Lang v. Sec'y of Health & Human Servs., No. 17-995V, 2020 WL 7873272, at \* 10 (explaining that "prior decisions by myself and other Special Masters have found that postponing treatment for a limited number of months is not per se dispositive of whether onset of shoulder pain occurred within the specified time period for a SIRVA"); Tenneson v. Sec'y of Health & Human Servs., 142 Fed. Cl. 329 (2019) (finding that the special master did not abuse her discretion in finding onset of a SIRVA was within 48 hours of vaccination despite an emergency department encounter that recorded normal range of motion of the extremities). Under the Vaccine Act, a special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period." § 300aa-13(b)(2). In that regard, I have considered the record as a whole, including the contemporaneous medical records and the testimony of the three witnesses, to reach a conclusion with respect to onset.

I first note that I find all three of the witnesses credible overall. Petitioner testified that he experienced "immediate" shoulder pain following his vaccination, which is consistent with what he reported to his physician the first time he was treated for his shoulder condition. (Tr. 10-11; Ex. 3, p. 442.) Moreover, both Ms. DiEgidio and Mr. Maresh provided testimony that broadly corroborated that petitioner was experiencing shoulder pain well in advance of the time at which he first formally sought treatment. (Tr. 85, 98-99, 105.) Mr. Maresh, in particular, had a specific recollection of helping petitioner with his trash in mid-to-late September. (Tr. 107-08.) Respondent's motion response does not grapple with the corroborating witness testimony at all. (ECF No. 65, pp. 9-10.)

Although the record reflects several medical encounters during October and November of 2018 wherein petitioner's shoulder pain was not documented, this largely reflects merely an absence of relevant notations rather than the presence of contradictory notations. Accord Kirby, 997 F.3d at 1382-83 (rejecting the premise that medical records are complete as to all a patient's conditions); Murphy, 23 Cl. Ct. at 733 (placing less significance on the absence of a reference to a condition). Respondent stresses petitioner's November 6, 2018, encounter. He argues that this encounter documented a normal musculoskeletal exam. (ECF No. 65, p. 9 (citing Ex. 3, pp. 429-30).) However, I do not agree that the notation within the November 6, 2018 medical record ("Musculoskeletal: He exhibits no edema") is sufficient to evidence an examination of the shoulder. Accord Kirby, 997 F.3d at 1383 (rejecting the argument that the notation "Neurological: Not Present-Dizziness" evidenced a complete neurologic exam); Tenneson, 142 Fed. Cl. 339-40 (finding the special master did not err in accepting the petitioner's testimony that no shoulder exam occurred in treatment of kidney stones despite a record documenting "non-tender," "nrml ROM," and "no pedal edema" under "extremities"). Petitioner testified that no exam of his shoulder was conducted at that encounter. (Tr. 23.)

I do not agree with respondent's contention that petitioner's explanation for the absence of any notation of shoulder pain between September and December of 2018 "defies logic." (ECF No. 65, p. 10.) Petitioner reasonably concluded based on his interactions with his physicians that his shoulder pain was not relevant vis-à-vis the specific purpose of his various encounters, which were for a sleep study, a blood pressure check, mental health counseling, and a follow up for hyperthyroidism. (Tr. 14-16, 18, 21-22, 59-60; Ex. 3, pp. 411, 435.) In particular, he was assured by his pulmonologist that his shoulder pain did not affect the efficacy of his sleep study, and when he reported his shoulder pain to his primary care provider, he told her that he still felt the pain would resolve on its own, effectively disclaiming a need for treatment at that time. (Tr. 18-19, 22-23, 63.)

The most concerning document from this period is petitioner's sleep study questionnaire. (Ex. 3, pp. 395-97.) This document potentially carries significant weight as a document completed by petitioner himself. *E.g. Demitor v. Sec'y of Health & Human Servs.*, No. 17-564V, 2019 WL 5688822, at \*10 (Fed. Cl. Spec. Mstr. Oct. 9, 2019) (stressing a handwritten intake form because "it cannot be said to reflect any

transcription mistake or miscommunication"). While petitioner's medical encounter records do not include any finding or notation incompatible with the ongoing presence of shoulder pain, petitioner's questionnaire specifically prompted petitioner to mark whether he was experiencing any joint pain, which he did not do. (Ex. 3, p. 397.) Moreover, the complete absence of any reference to shoulder pain in response to any of the questionnaire prompts is in tension with petitioner's testimony that he was concerned that his shoulder pain would affect the sleep study.

However, considering the record as a whole, I cannot conclude that this questionnaire is dispositive of whether shoulder pain or dysfunction was existing at that time. Petitioner plausibly testified that the absence of a specific prompt regarding the shoulders explained why he did not report his shoulder pain within that document. (Tr. 54-57.) Moreover, the purpose of the sleep study was to evaluate petitioner for longstanding issues pertaining to sleep apnea. (Ex. 3, p. 327 (May 28, 2018 encounter documenting history of obstructive sleep apnea and recommending "repeat testing given his weight gain and length of time since prior testing").) In contrast, petitioner's testimony suggests that at the time of his sleep study, he felt that his shoulder pain. which had begun only about two weeks prior, was a temporary issue that would resolve. (Tr. 13-14.) Even accounting for his concern regarding the efficacy of the sleep study, it would not necessarily be unreasonable for petitioner's completion of the questionnaire to reflect his longstanding sleep patterns rather than his more acute shoulder issue. In any event, respondent did not raise any specific argument with respect to the sleep study questionnaire in his motion response (ECF No. 65, pp. 9-10) after specifically questioning petitioner about the document during the hearing. (Tr. 53-57.)

Though not binding on me, I have considered the cases cited by respondent as comparable. However, I agree with petitioner that they are distinguishable and therefore do not counsel a finding against petitioner given the facts of this case. In both Rose and Bulman, the Chief Special Master was persuaded that during the period the petitioners' shoulder pain went unrecorded, they had undergone physical examinations that would have detected the alleged shoulder condition if it had been present. Rose, 2022 WL 4128908, at \*4 (noting "a thorough physical examination with abnormalities noted only in the cervical and lumbar spine and no tenderness, swelling or limited range of motion in the shoulders."); Bulman, 2021 WL 4165349, at \*3-4 (noting "the report from a full physical examination" that specified normal findings with respect to the extremities). Additionally, the Chief Special Master remarked in both cases that the petitioners' allegations were further hampered by the fact that the complaints of postvaccination pain that were included in the medical record were vague or general. Rose, 2022 WL 4128908, at \*4 (noting the treatment records "consistently make generalized references to her shoulder pain beginning after vaccination without specifying a more precise onset"); Bulman, 2021 WL 4165349, at \* 4 (noting petitioner's allegations "are further undermined by the lack of specificity in the medical records"). In Pitts, the petitioner had explicitly indicated at his physical therapy evaluation that the onset of his shoulder pain began "about 1 week" after his vaccination. 2020 WL 2959421, at \*4. That specific notation was ultimately credited in placing the date of onset at one-week post vaccination. Pitts, 2023 WL 2770943, at \*9. In this case, there is no thorough

physical exam documented during the initial post-vaccination period from September to December 2018 comparable to what had been done in both *Rose* and *Bulman*. And, whereas the treatment records in these prior cases were either vague (*Rose* and *Bulman*) or explicitly placed onset outside of the 48-hour period (*Pitts*), this petitioner was clear in reporting an "immediate" post-vaccination onset to his medical providers, consistent with his testimony. (Tr. 10-11; Ex. 3, p. 442.)

Accordingly, considering the parties' arguments and the record as a whole, there is preponderant evidence that petitioner suffered onset of left shoulder pain within 48 hours of his September 27, 2018 flu vaccination.

## b. SIRVA QAI Criteria (i), (iii), and (iv), and factor(s) unrelated to vaccination

As explained above, in addition to demonstrating that his shoulder pain arose within 48 hours of his vaccination, petitioner must also demonstrate that he has no relevant history of shoulder pain or dysfunction that could explain his symptoms, that his condition was limited to the shoulder affected by his alleged SIRVA, and that no other condition is present that would otherwise explain his symptoms. 42 C.F.R. § 100.3(c)(10). Petitioner asserts that he has satisfied all of these criteria and respondent has raised no argument to the contrary. Additionally, I have reviewed the entire record and conclude that these three criteria have been met. Once a petitioner has met his initial burden of proof in demonstrating the presence of a Table injury, respondent may still demonstrate that the injury was nonetheless caused by a factor unrelated to vaccination. § 300aa-13(a)(1)(B); Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1367 (Fed. Cir. 2013). Here again, respondent has not raised any such argument and my own review of the record does not find any other potential cause of petitioner's condition.

### VI. Conclusion

After weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA resulting from the flu vaccination he received on September 27, 2018. Accordingly, petitioner is entitled to compensation for his SIRVA. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master